

**REMARKS**

**Amendment of the Claims and Claim Status**

Claims 1-48 are pending in this application. Applicants wish to highlight that Claims 2-20, 25, 28, and 30-48 have been withdrawn, and Claims 1, 21-24, 26-27, and 29 remain under consideration. Claims 24 and 26 were inadvertently omitted, or seemingly so, from the listing of claims under consideration in the June 6th, 2006 Office Action.

As Examiner may recall, Applicants elected to prosecute Group IV (Claims 14-32) for the time being. *See* Applicants' December 1st, 2005 communication. Applicants subsequently elected "Novispirin G10" as the anti-microbial peptide moiety and "*Pseudomonas spp.*" as the target microbial organism for initial examination. *See* Applicants' March 3rd, 2006 communication. As such, Claim 24 is believed to fall within these parameters as the class of cariogenic organisms encompass certain *Pseudomonas spp.*, e.g. *Pseudomonas aeruginosa*. Claim 26, being part of Group IV, should also be amongst the claims being considered as the claimed invention comprises "a peptide selected from the group consisting of histatin 5, dhvar 1, protegrin PG-1, and Novispirin G10."

Claims 16, 18, 20, and 22 are amended herein to substitute the language "as shown in" with "of" for improved clarity.

No new matter has been introduced by the foregoing amendments.

**Double Patenting**

Claims 1, 23, 27, and 29 have been provisionally rejected under 35 U.S.C. 101 as being unpatentable over Claims 1, 21, 24, and 26 of copending U.S. Application no. 10/706,391. Claim 21 is provisionally rejected under the doctrine of nonstatutory obviousness-type double patenting as being unpatentable over Claim 20 of U.S. Application no. 10/706,391. Applicants respectfully submit that the double patenting issue with regard to the above claims is not yet ripe for consideration since Application no. '391 is still pending.

**Priority**

It is set forth in the Office Action that Applicants allegedly fail to comply with the provisions set forth under 35 U.S.C. 120 for receiving benefit of U.S. application no.

09/910,358. Applicants respectfully submit that their claim to the priority date of Application no. '358 is proper. Nevertheless, to expedite prosecution, Applicants would like to address the disclosure of the references cited in the Office Action rather than rely on the priority of the present invention to overcome the prior art rejection. Applicants expressly reserve the right to revisit the priority issue and assert the priority of Application no. '358 at a later stage.

**Rejection under 35 USC §103**

**Claims 1, 21-23, 27, and 29 over Lehrer et al. in view of Goldenberg**

Claims 1, 21-23, 27, and 29 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lehrer et al. (U.S. 6,492,328) in view of Goldenberg, which was designated as U.S. 5,332,627 in the June 6th Office Action. It is Applicants' belief that the art being referenced was U.S. 5,332,567 rather than No. 5,332,627, which is directed to a "field emission type emitter." Applicants respectfully traverse this rejection for the following reasons:

Under MPEP 2143.03, "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." The present invention, as recited in Claims 1, 21-24, 26-27, and 29, provides a "targeting moiety ...coupled to (an) antimicrobial peptide moiety" wherein the "(targeting moiety) recognizes a target microbial organism." Lehrer et al., while disclosing the antimicrobial properties of Novispirin G10, does not contemplate the coupling of novispirin to a targeting moiety, *i.e.* the targeting of an antimicrobial, as is characteristic of the present invention.

Goldenberg likewise fails to cure the deficiency of Lehrer et al.'s disclosure. The immunoconjugates contemplated in Goldenberg are antibodies/fragments which are chemically linked to a drug, toxin, or detecting agent. Such chemical conjugation methods result in "non-specific linkage of pharmaceutical reagents to unknown sites on the antibody molecule used for targeting," creating the very problems that the present invention was designed to overcome: a) inefficient linkage, b) non-uniform products, c) reduced or lost targeting capability from poor linkage position, d) reduced or lost therapeutic capability from poor linkage position. *See* ¶7 of the instant specification. The present invention, having a targeting moiety coupled to an antimicrobial peptide moiety, is bifunctional, *i.e.* recognizing a target microbial organism and retaining its antimicrobial effect.

Conversely, Lehrer's disclosure of novispirin cannot cure the Goldenberg's failure to teach the use of novispirin in its immunoconjugates by virtue of the inherent difficulties associated with producing a specifically targeted antimicrobial. Immunoconjugation, as described in Goldenberg, is a complicated procedure for which the majority of proteins will not serve as suitable vehicles due to their loss of native or active conformations. One of ordinary skill in the art, armed with Goldenberg and Lehrer's disclosures, would not have been led to attempt a conjugation of novispirin with a targeting moiety and certainly would have no reasonable expectation of success should an attempt have been made. In light of the above, Applicants believe the present invention to be patentable over Lehrer et al. and Goldenberg. Withdrawal of the rejection is respectfully requested.

Claims 1, 21-23, 27, and 29 over Lehrer et al. in view of Shi et al.

Claims 1, 21-23, 27, and 29 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Lehrer et al. (U.S. 6,492,328) in view of Shi et al. (U.S. Patent Publication 2004/0052814A1). Applicants respectfully submit that U.S. '814A1 and the present application were, at the time the present invention was made, subject to an obligation of assignment to the same organization(s)/business entity(ies), thereby disqualifying U.S. '814A1 as prior art under 35 U.S.C. 103 in accordance with MPEP 706.02(l)(2). As Examiner so aptly noted, the remaining reference Lehrer et al. only disclose the use of novispirin for treating bacterial, fungal, and protozoan infections and neither teach nor suggest the presently claimed composition. Withdrawal of the rejection is therefore respectfully requested.

Claim Objections & Rejection under 35 USC §112, 2nd paragraph

Claims 1, 21-23, 27, and 29 are objected to for allegedly being drawn to non-elected inventions. Applicants are uncertain which aspect of the above claims Examiner finds objectionable since Claims 1, 21, 23, 27, and 29 clearly fall within Group IV, which Applicants earlier elected to prosecute. Likewise, Claims 23, 27 and 29 were rejected under 35 U.S.C. 112 as being indefinite for reciting language drawn to non-elected inventions. In order to address Examiner's concerns, Applicants would be most appreciative if Examiner could elaborate on the bases for the above objection and indefiniteness rejection pursuant to MPEP 706.03(d), which provides, "whenever possible, (Examiner should) identify the particular term(s) or

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limitation(s) which render the claim(s) indefinite and state why such term or limitation renders the claim indefinite."

In view of the foregoing, it is believed that all claims now pending in this Application are in condition for allowance. Should the Examiner have any continuing objections, the Applicant respectfully asks the Examiner to contact the undersigned at 415-442-1490 (direct line) in order to expedite allowance of the case. Authorization is granted to charge any outstanding fees due at this time for the continued prosecution of this matter to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 (matter no. 061818-5512-US01).

Respectfully submitted,

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